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A pilot randomised controlled trial of a multimodal supportive care (ThriverCare) intervention for managing unmet supportive care needs in men with metastatic prostate cancer on hormonal treatment and their partner/caregivers

Original Research

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Running Head: A multimodal supportive care intervention

Key words: Supportive Care; Patient Reported Outcomes; Metastatic Prostate Cancer; Intervention; Randomised Controlled Trial; Unmet Needs, Partner/Caregivers

Abstract

Purpose: Men with metastatic prostate cancer experience high levels of unmet supportive care needs in current healthcare delivery. We set out to determine the effectiveness of a multimodality supportive care (ThriverCare) intervention on the prevalence of unmet supportive care needs for men and their partner/caregivers.

Methods: A prospective parallel group, pilot randomised controlled pilot trial in 4 hospitals in Scotland. 38 participants with radiologically proven metastatic prostate cancer disease and 10 partners/caregivers were recruited into the study. A two arm 1:1 study design compared the usual standard of care (SC) approach to SC plus ThriverCare intervention. The primary outcome was the Supportive Care Needs Survey at 3 months of intervention.

Results: There was no statistical significant difference in the prevalence of unmet supportive care needs between the intervention group and the usual SC group at baseline p=0.112, however a statistically significant difference was observed at 3 months, indicating that the prevalence of unmet supportive care needs were less in the intervention group (1.13, SD 2.5) compared to the usual SC (6.17, SD 7.05), p=0.002.

Conclusion: ThriverCare appears to improve the supportive care experience of men with metastatic prostate cancer on hormonal treatment and their partner/caregivers. Our results accentuate that no longer one size of care delivery fits all, care must be responsive and adaptable to meet the individual needs of people affected by cancer to thrive.

Introduction

Androgen deprivation therapy (ADT) for metastatic prostate cancer remains the mainstay of treatment and has been proven to be effective in controlling disease (Sternberg et al., 2013). The majority of men face a range of physical and psychological problems that can have a profound decrement on quality of life and exacerbate the need for supportive care (Cockle-Hearne et al., 2013; King et al., 2015; Paterson et al., 2017; Watson et al., 2016). The treatment specific side effects include hot flushes, osteoporosis, fatigue, sexual dysfunction, changes in muscle mass, adiposity, and psychological effects such as, mood disturbance, cognitive impairment, difficulties with self-image and masculinities (Fitzpatrick et al., 2014). Men affected by metastatic prostate cancer are likely to have a long illness pathway, as well as the individual burden to patients and their partner/caregivers with the associated side-effects, and this represents a burden on healthcare resources internationally (Carter et al., 2011; Chambers et al., 2018; Paterson et al., 2015a; Paterson et al., 2017).

Systematic reviews in the area of unmet supportive care needs in men affected by prostate cancer underscore that many can experience on-going and unresolved concerns related to psychological needs, managing physical side-effects and a lack of information and support (Chambers et al., 2018; King et al., 2015; Paterson et al., 2015b). Moreover, recent evidence acknowledges that current delivery of care is failing to provide a person-centred model of supportive care for men and their partner/caregivers affected by metastatic prostate cancer (Chambers et al., 2018; Paterson et al., 2017). National and international cancer reforms (McCabe et al., 2013) recognise that men affected by metastatic prostate cancer continue to experience a range of complex unmet supportive care needs even in twenty-first century healthcare (Carter et al., 2011; Chambers et al., 2018; Paterson et al., 2017).

Supportive care needs are defined as requirements for care arising during treatment and illness to manage symptoms and side-effects, enable adaption and coping, optimise understanding and informed decision-making, and minimise decrements in functioning (Hui, 2014). Supportive care is a person-centred approach to the provision of the necessary services for those living with or affected by cancer to meet their informational, spiritual, emotional, social, or physical needs during diagnosis, treatment, follow-up and into survivorship (Hui, 2014). One approach to quality of life evaluation that assesses supportive care requirements is needs assessment (Bonevski et al., 2000). A large body of evidence now exists which focusses on the prevalence of unmet supportive care needs in men with prostate cancer (Cockle-Hearne et al., 2013; King et al., 2015; Paterson et al., 2017; Primeau et al., 2017; Watson et al.,

2016), including those with metastases on ADT (Chambers et al., 2018; Paterson et al., 2017; Primeau et al., 2017) but little or no evidence has been reported to address possible interventions (McCabe et al., 2013; Watson et al., 2016). An innovative pilot multimodal supportive care intervention, called ThriverCare (Paterson et al., 2017; Primeau et al., 2017) was designed in the present study and tested through a pilot randomised controlled trial. Thrivercare was informed by the Prostate Cancer Model of Consultation as the underpinning theoretical study model (Paterson and Nabi, 2016). ThriverCare was developed to address unmet care need concerns, normalise follow-up treatment experience, and move beyond prostate cancer survivorship to cancer thrivership (Weiner et al., 2005). This pilot randomised controlled study aimed to provide supporting evidence for the acceptability and usefulness of the ThriverCare intervention for patients and their partners/caregivers affected by metastatic prostate cancer compared to the usual standard of care.

Hypothesis

We tested the hypothesis that the ThriverCare intervention would improve 1) supportive care needs, 2) psychological outcome, 3) health-related quality of life and 4) self-efficacy in comparison to patients and their partner/caregivers receiving the usual standard of care.

Patients and Methods

Design

This was a pilot parallel randomised controlled trial conducted according to the Consolidated Standards of Reporting Trials (CONSORT) statement guidelines (Schulz et al., 2010).

Participants

Eligible participants were diagnosed with metastatic prostate cancer on primary androgen deprivation therapy (ADT), aged 18 years or over, self-assessed written and verbal English proficiency and, able to provide written informed consent. Radionuclide bone scan/computed tomography (CT) scan or magnetic resonance imaging (MRI) confirmed metastatic disease in all the participants.

Exclusion criteria were: men lacking inclusion criteria, men with dual cancer and those on chemotherapy or following relapse of disease.

Setting

The study was undertaken at four hospitals in Scotland from March 2016 to April 2017. The healthcare provision serves a geographical area which consists of a predominantly rural and urban population of white ethnicity (405,721) published by the General Register Office for Scotland. The study had NHS Ethical approval (16/ES/0024).

Sample Size

The consortium design of study is shown in **Figure 1**. As pilot trials do not have the same objectives as a main trial, setting the sample size in the same way by utilising a formal power calculation is not appropriate (Whitehead et al., 2016). However, we carefully considered the optimum sample size justification for the pilot study using guidance from (Billingham et al., 2013; Whitehead et al., 2016). For the main trial designed with 90% power and two-sided 5% significance, we followed a pilot trial sample size of 25 per treatment arm for a standardised small effect size (0.2).

Recruitment Process

Patients were randomly assigned 1:1 to either usual standard of care (SC) or SC plus ThriverCare, see **Figure 2**. Block randomization was used to reduce bias and was generated in a permuted block design (Kang et al., 2008). Participants were randomly assigned and notified of allocation after completion of consent and baseline study questionnaires. As active patient participation is required as part of the intervention, a traditional single-blind (i.e. patient level) or double-blind RCT (i.e. patient and investigator level) was not deemed feasible in the context of this pilot study. To mitigate the adverse effects of blinding bias, the patient information sheets were designed to avoid any reference to the 'intervention group' or 'control group'. Patients were only informed that they were randomly allocated to one of two different methods of supportive care delivery.

Intervention Group: ThriverCare

The intervention was developed using the Medical Research Council Framework for complex interventions (Craig et al., 2008) and the six steps in quality intervention development (6SQuID) (Wight et al., 2015). The intervention was informed by the Prostate Cancer Model of Consultation (Paterson and Nabi, 2016) and comprised four main components: 1) informational materials, 2) holistic needs assessment, 3) individualised self-management care plans, and 4) group-based seminar. The

intervention and associated materials were developed in consultation with multidisciplinary healthcare experts involved in prostate cancer and patient's representatives.

Informational materials

Participants were provided with a custom-made evidence-based self-management booklet entitled "*A Prostate Cancer Guide to Thrivership: Men it is time to Thrive*" (Supplementary Information). The information booklet covered the following general topics: how to self-care, managing side-effects of ADT, nutrition and exercise, relationships and sexual well-being, healthy lifestyle approaches and community-based support resources.

Holistic Needs Assessment

An individualised, nurse-led face-to-face session was conducted across the four hospitals at baseline and at three months. Patients and their partners/caregivers completed the Macmillan's Holistic Needs Assessment (HNA) questionnaire (Doyle and Henry, 2014) ten minutes before the nurse-led session, at baseline and at three months. The HNA questionnaire information was then directly used in the consultation to tailor individualised self-management care plans of each patient and their partner/caregiver. The consultation included the discussion of concerns/problems, determining an individualised strategy with realistic goals and expectations which could be incorporated into daily life. Consultation sessions were concluded by summarising the main issues, making necessary referrals and appointments for follow-up including open door access using emails.

Self-management care plans

Self-management care plans were formatted as written documents provided to the participants at the end of the discussion of the HNA in the nurse-led session. Further copies of the care plans were provided to the General Practitioner and filed in the patients' medical case notes, for quality assurance. The Prostate Cancer Model of Consultation (Paterson and Nabi, 2016) and evidence based guidelines for nurse-led survivorship care (Paterson et al., 2015a) were used to support the development of shared self-management care plans. The prostate cancer care model (Paterson et al., 2015a; Paterson and Nabi, 2016) enabled standardization of evidence-based self-management interventions for precise intervention content. The nurse-led session took place in an out-patient hospital clinic room and lasted approximately 30 minutes.

Group-based seminar

The self-management seminar included the following topics: 1) introduction to ADT and potential side-effects, 2) self-managing side-effects, 3) managing emotions and mind changes, 4) erectile dysfunction and relationships, 5) nutrition and exercise, 6) finance and benefits, 7) relaxation and stress management, and 8) sign-posting to community-based services and open question session (**Figure 3**). The seminar was led by a senior prostate cancer specialist nurse, physical activity instructor and a trained counsellor.

Standard of care/control group: Patients in the control group received the usual standard of care as was offered at the hospitals or by their usual clinicians. This involved baseline and three monthly outpatient clinic review and does not include any elements of the ThriverCare intervention.

Data collection

All participants completed the baseline questionnaires on the day of randomization and one further questionnaire three months later. The outcomes measures at baseline and at three months were administered by a research assistant not involved in the intervention delivery. Thirty-three semi-structured interviews were conducted to explore their experience of supportive care and these data have been published elsewhere (Primeau et al., 2017).

Clinical and demographic data

Demographic and clinical data were collected at the start of the study and included: age, marital status, socio-economic (Scottish Index of Multiple Deprivation), employment status, diagnosis, stage of disease, prostate specific antigen (PSA), Gleason score, length of time since diagnosis, treatment, and existing co-morbidities. Only demographic data was collected from partners/caregivers.

Outcome measures

All self-report standardized outcome measures were psychometrically validated, responsive, acceptable, and have been used in this patient population.

Primary outcome

Unmet supportive care needs

Supportive Care Needs Survey (SCNS-SF34) is a multidimensional self-report questionnaire that evaluates 34 patient needs that fall under the following five domains: health system and information, psychological, physical and daily living, patient care and support, and sexuality.

Secondary outcomes

Self-efficacy

Self-management Self-Efficacy Scale (SE Scale) provides an assessment of participant's belief and confidence to perform their self-management. Self-efficacy is a general term used to describe the belief that one can perform a novel or a difficult task, or cope with adversity in various domains of human functioning.

Health-related quality of life

EORTC Quality of Life (QLQ C30) *and* (PR25) is an integrated measurement system for quality of life in cancer participants.

Psychological outcome

Hospital Anxiety and Depression Scale (HADS) assesses anxiety and depression in non-psychiatric patients.

Statistical approach

All analyses were conducted in SPSS Statistics for Windows version 21.0 (IBM Corp., http://www-03.ibm.com/software/products/en/spss-statistics). Descriptive statistics were used to summarize outcome measures, baseline demographic and clinical characteristics of patients randomized to each study arm. Prior to the analysis, variables were examined for accuracy of data entry, missing values and the assumptions of the proposed analysis. Basic exploratory statistical analysis of *indicative findings* was undertaken to characterise the cohort (Tabachnick and Fidell, 2007).

Results

Of the 73 patients approached to take part in the study, 25 declined participation. There was a statistically significant difference in age between the consented group 75 years (SD 5.9) and non-consented group 84 years (SD 6.6) $p<0.01$. Moreover, we did not observe any statistically significant difference in the duration of ADT or time since diagnosis between the two groups $p>0.05$. The reasons for declining participation included: a lack of time due to being a main carer, dislike of completing questionnaires, patients reported that they felt too old, and too much going on with treatment, see **Figure 1** for Consort diagram.

There were no statistically significant differences in age, employment, Gleason score, number of co-morbidities, PSA levels between the intervention and standard of care groups, see **Table 1.** We observed a statistically significant difference in socio-economic ($p=0.048$) and marital status ($p=0.005$) between the intervention and control groups, but overall the characteristics were well-balanced between the two groups. Time since diagnosis ranged from seven to 56 months.

Primary outcomes

There was no statistically significant difference in the prevalence of unmet supportive care needs between the intervention group and usual SC group at baseline ($p=0.112$). A statistically significant difference was observed at three months, indicating that the prevalence of unmet supportive care needs were less in the intervention group (1.13, SD 2.5) than compared to usual SC (6.17, ± 7.05) $p=0.002$ shown in **Figure 4**. The most common unmet supportive care needs identified through baseline evaluation included physical symptoms such as fatigue (18.8%), pain (16.7%), fear of the cancer spreading (27.1%), uncertainty of the future (29.2%), anxiety of death and dying (18.8%), changes in sexual feelings (23.0%), worries and concerns of those closest to you (29.9%), more choice about which cancer specialist you would like to see (25.1%), lack of self-management advice (23.0%), unmet informational needs (18.8%) and not being informed of test results (22.9%).

We observed the greatest improvements in the following domains of unmet needs following the ThriverCare Intervention at three months (**Table 2**): physical symptoms (pain 0%, fatigue 7.7%), fear of the cancer spreading (7.7%), fear of death and dying (0%), changes in sexual feelings (7.7%), concerns of those closest to you (7.7%), more choice about which cancer specialist you see (0%), informational

needs (0%), self-management advice (0%), and being informed of test results as soon as is feasible (7.7%). In the control group 205 unmet supportive care needs were reported, and 14 unmet needs in the intervention group at three months, noteworthy all the unmet needs in the intervention group were scored as "low unmet need" (**Table 2**).

Secondary outcomes

No statistically significant differences were observed between the two groups with regards to, or within group score changes on self-efficacy (p=.212), anxiety (p=.101), depression (p=.489) and health related quality of life (p=.886) over time (**Table 1**).

Discussion

A significant proportion of men affected by metastatic prostate cancer encounter a broad scope of concerns and unmet needs, despite ongoing follow-up care in a range of international counties which include Australia, UK, and Canada (Carter et al., 2011; Chambers et al., 2018; Paterson et al., 2017; Paterson et al., 2015b). To our knowledge, this is the first pilot RCT study that compared a multimodal supportive care (called ThriverCare) intervention for men and their partners/caregivers and compared this to the usual SC. We hypothesized that the intervention would reduce unmet supportive care needs, improve quality of life, reduce anxiety and depression and improve self-efficacy. Our primary outcome was supportive care needs. We observed a statistically significant main group effect on the prevalence of unmet supportive care needs over time, in favour of the ThriverCare intervention. Integrating the evidence-based seminar with the use of Holistic Needs Assessment (HNA) questionnaires in clinical practice permitted a tailored, personalised model of care and targeted self-management plans. Areas of supportive care which demonstrated the most improvement included physical symptoms, existential concerns (fear of death), choice of which cancer specialist patients see, informational needs and self-management advice was observed at three months in the intervention group. Supportive interventions which incorporate direct interaction with specialist healthcare professionals and feature individually tailored self-management have shown promise in improving patient outcomes elsewhere (Bourke et al., 2012; Menichetti et al., 2016; Parahoo et al., 2015) but our study is the first to demonstrate a direct improvement on the prevalence on unmet supportive care needs in patients with metastatic prostate cancer.

The intervention did not have any impact on secondary outcomes which included, health-related quality of life, anxiety and depression, or self-efficacy over time. While self-efficacy is a prevalent construct used in existing intervention studies, it has inconsistent outcomes (Hofman, 2013). Very few studies (Moore et al., 2015) that have incorporated self-efficacy reported that self-efficacy was not affected by, or could explain the intervention effect; similar to the indicative findings in the current study. Moreover, our results are in keeping with other supportive care interventions in prostate cancer populations, in so far that they also did not demonstrate any changes in health-related quality of life or psychological outcome scores (Carmack Taylor et al., 2004; Northouse et al., 2007). Reasons for no statistically significant improvements in these outcomes remains unknown and may need further exploratory studies in this area (Primeau et al., 2017).

Patients are increasingly completing standardised patient reported outcome (PRO) questionnaires about their symptoms, functioning, well-being, supportive care needs and these PRO data are being used along with other clinical information to screen for conditions, monitor progress, and inform patient management (Greenhalgh, 2009; Jensen et al., 2014). Unmet needs of people affected by cancer often mediate a poorer quality of life, including greater physical impairment and symptom burden, anxiety and depression, and persistent supportive care requirements over time (King et al., 2015). These consequences may be under-recognized and under-treated in oncology practice and this was evident in the standard of care group in the present study. Globally, cancer organizations have published supporting recommendations about the pilot and beneficial effects of using PROs in routine clinical practice (Abernethy et al., 2010) which underpinned our intervention design.

A number of studies have examined the clinical utility of PRO holistic needs assessment (Bonevski et al., 2000). To the best of our knowledge, this is the first pilot RCT to demonstrate an improvement in supportive care experience for men affected by metastatic prostate cancer through the use of PRO HNA's in clinical practice, elsewhere studies are currently on-going (Snowden et al., 2015; Stanciu et al., 2015). As a strengthen to our study, we implemented the Prostate Cancer Model of Consultation as part of the HNA process (Paterson and Nabi, 2016) which enabled precise standardization of evidence-based self-management interventions tailored to the individual area of need. Arguably, the completion of HNAs questionnaires in clinical practice alone, are of no benefit or can worsen unmet supportive care needs experience, if the clinician does not discuss the unmet needs information documented in the consultation, or if the clinician does not have access to precise evidence-based self-management

interventions to support or advice the patient appropriately. A methodological limitation of studies elsewhere (Snowden et al., 2015; Stanciu et al., 2015) is that they do not clearly evidence the standardization of the intervention content following the completion of the HNA. Inevitably, this will create the opportunity for bias because healthcare professionals vary in experience, knowledge and expertise in their ability to develop shared self-management plans to address unmet physical, emotional, spiritual, environmental, social, sexual, financial and cultural needs.

A statistically significant difference was observed for marital status and socio-economic status between the intervention and control group, which may have affected supportive care, for example, the informal care provided by the spouse. However, this seems unlikely as there was no statistically significant difference in the prevalence of unmet supportive care needs between the intervention and control group at baseline. Furthermore, there was no statistically significant difference in co-morbidities between the two groups, as we recognise multiple health conditions might increase the need and provision for supportive care (Holm et al., 2014). Regardless of the clinical characteristics and time since treatment, we observed men with metastatic prostate cancer in the control group continued to experience a range of unmet supportive care needs at a follow-up of three months related to, physical and psychological problems, fear of cancer spreading, uncertainty of the future, intimacy and sexual needs, and a lack of personalised holistic care, in keeping with the existing evidence base (Carter et al., 2011; Chambers et al., 2018; King et al., 2015; Paterson et al., 2015b).

One of major findings of this pilot RCT study is that through targeting self-management plans to individual needs is one of the most important issues to be considered. Broad targeting interventions are at risk of including men with dissimilar needs, which can affect intervention adherence, study attrition and dilute effect. Men's needs will inevitably differ across the disease, with emotional distress and uncertainty of the future being most salient around the time of diagnosis, and symptom problems and self-management critical during treatment. We argue, optimising supportive care can be achieved by tailoring interventions informed by the ThriverCare to identify individual needs/concerns and address each patients requirements individually (Paterson and Nabi, 2016). Individual needs and concerns will differ in terms of social support, education, economic status, religion, and ethnicity, and such factors should also be taken into account explicitly in targeting and evaluating outcomes (Paterson and Nabi, 2016).

The participation rate into the trial was 67% and similar to other studies in this patient group. However, we observed a statistically significant difference in age between the consent and non-consents groups. Typically, clinical trials conducted in the adult population include patients between the ages of 18 and 65 years, and often elderly patients over >65 years are poorly represented. Our study highlights some of the issues which elderly people with metastatic disease expressed as reasons for non-participation into the trial. Time restraints, social circumstances, age and physical activities were important barriers to the participation in the present study.

Several limitations are worth noting. First, the study had a small sample size and limited follow-up. Second, we lacked information on the actual self-management behaviours performed by participants and how this impacted upon their experience of supportive care. Third, this study was biased in favour of white participants and as a result, some caution should be taken in the interpretation of these findings and requires the study to be replicated with a larger multi-centre sample, and men from minority groups to be equally represented.

Conclusion

This study has demonstrated that the novel ThriverCare intervention for men and their partners/caregivers affected by metastatic prostate cancer improves the prevalence of unmet supportive care needs over time. This should inform management and care planning of men with metastatic disease on androgen deprivation therapy. Future studies in other tumour groups should carefully consider targeting individuals with significant issues or unmet needs to strive to deliver a model of care that is individualised and flexible. Our results accentuate that no longer one size of care delivery fits all, care must be responsive and adaptable to meet the individual needs of people affected by cancer to thrive.

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Table 1 Clinical and Demographic Characteristics

	Standard care group (n29)	Intervention group (n19)	p Value
Age	77.5 (SD 6.2, min 66 – 93) years	74.9 (SD 8.2, min 60 – 86) years	.177
SIMD*			
Most deprived	3 (10.3%)	0 (0%)	.048*
2	2 (6.9%)	5 (26.3%)	
3	6 (20.7%)	3 (15.8%)	
4	15 (51.7%)	5 (26.3%)	
Least Deprived	3 (10.3%)	6 (31.6%)	
Marital status	Widowed 11 (37.9%) Married 18 (62.1%)	Single 1 (5.3%) Widowed 3 (15.8%) Married 15 (78.9%)	.005*
Employment status	Retired 29 (100%)	Retired 19 (100%)	.203
Number of co-morbidities	2.4 (SD 2.8)	2.7 (SD 2.6)	.377
Gleason Score			.202
6	0 (0%)	0 (0%)	
7	2 (6.9%)	6 (31.6%)	
8-10	2 (6.9%)	0 (0%)	
No pathology	21 (86.2%)	7 (68.4%)	
PSA diagnosis	131.2 (SD 208.2)	319.2 (SD 380.6)	.052
PSA Recent	12.9 (SD 23.4)	20.7 (29.5)	.363
Psycho-social constructs			
Anxiety baseline	2.9 (SD 3.4)	2.3 (SD 3.8)	.686
Anxiety 3M	2.1 (SD 1.9)	2.4 (SD 4.6)	.102
Depression baseline	3.6 (SD 3.6)	3.6 (SD 3.1)	.760
Depression 3M	4.1 (SD 4.4)	3.6 (SD 3.6)	.489
Self-efficacy	3.5 SD .8)	3.7 (SD.37)	.364
Self-efficacy 3M	3.6 (SD .6)	3.7 (SD .12)	.212
Health Related Quality of Life			
Global QoL	73.5 (SD 22.2)	76.4 (SD 23.4)	.788
Global QoL 3M	79.6 (SD 23.9)	81.9 (SD 19.6)	.866
Physical function	77.8 (SD 24.9)	81.9 (SD 19.9)	.536
Physical function 3M	82.8 (SD 20.7)	83.9 (SD 20.9)	.451
Role Function	78.4 (SD 29.5)	81.4 (SD 29.4)	.521
Role Function 3M	88.1 (SD 31.4)	80.2 (SD 28.0)	.316
Emotional Function	87.5 (SD 15.6)	82.4 (SD 15.7)	.421
Emotional Function 3M	84.1 (SD 12.4)	81.8 (SD 17.1)	.071
Cognitive function	82.7 (SD 16.0)	85.2 (SD13.0)	.582
Cognitive function 3M	84.1 (SD 12.6)	84.3 (SD 18.1)	.586
Social Function	85.7 (SD 19.1)	86.3 (SD 25.8)	.452
Social function 3M	80.5 (SD 26.7)	85.4 (SD 26.4)	.321
Fatigue	19.7 (SD .5)	19.7 (SD .8)	.521
Fatigue 3M	19.8 (SD .9)	16.7 (SD .8)	.564
Nausea and vomiting	1.7 (SD 6.9)	2.9 (SD 6.5)	.423
Nausea and vomiting 3M	2.3 (SD 6.2)	2.8 (SD 6.1)	.361
Pain	11.1 (SD 18.4)	5.8 (SD 26.3)	.502
Pain 3M	12.3 (SD 6.2)	4.7 (SD 26.7)	.191
Dyspnoea	12.5 (SD 19.9)	13.7 (SD 20.6)	.501
Dyspnoea 3M	19.0 (SD 17.8)	13.7 (SD 16.9)	.491

Insomnia	6.2 (SD 24.7)	4.6 (SD 23.9)	.224
Insomnia 3M	9.2 (SD 16.2)	5.6 (SD 20.6)	.236
Appetite loss	7.1 (SD 13.9)	7.8 (SD 18.6)	.267
Appetite loss 3M	9.5 (SD 25.1)	7.8 (SD 18.7)	.354
Constipation	15.4 (SD 24.8)	13.7 (SD 20.6)	.356
Constipation 3M	19.0 (SD 32.5)	21.6 (SD 28.7)	.451
Diarrhoea	9.2 (SD 23.0)	7.8 (SD 14.6)	.267
Diarrhoea 3M	8.2 (SD 23.1)	7.6 (SD 14.9)	.312
Financial Difficulties	2.3 (SD 8.7)	1.9 (SD 8.0)	.326
Financial Difficulties 3M	0 (SD .0)	1.9 (SD 8.0)	.412
Urinary symptoms	17.6 (SD 14.6)	17.6 (SD 14.6)	.312
Urinary symptoms 3M	23.6 (SD 9.6)	20.4 (SD 13.9)	.545
Bowel symptoms	5.5 (SD 8.7)	6.5 (SD 3.7)	.599
Bowel symptoms 3M	2.8 (SD 4.1)	4.1 (SD 7.1)	.512
Treatment symptoms	12.7 (SD 9.9)	9.7 (SD 11.6)	.170
Treatment symptoms 3M	20.8 (SD 9.5)	12.1 (SD 10.4)	.123
Sexual activity	13.1 (SD 21.9)	11.6 (13.7)	.830
Sexual activity 3M	12.5 (SD 15.9)	12.5 (SD 18.9)	.631
Sexual function	1.0 (SD .3)	0.8 (SD .2)	.859
Sexual function 3M	0 (SD .0)	0 (SD 0)	.696

*Scottish Index of Multiple Deprivation (1 most deprived – 5 least deprived)

Table 2. Prevalence of Unmet Supportive Care Needs at 3 Months

Domains of unmet supportive care needs		Low unmet need. I had little need for additional help. N (%)	Moderate unmet n had some need additional help. N (%
Pain	(standard)	2 (8.0%)	4 (16%)
	(Intervention)	0 (0%)	0 (0%)
Lack of energy/tiredness	(standard)	5 (20.0%)	1 (4.0%)
	(Intervention)	1 (7.7%)	0 (0%)
Feeling unwell a lot of the time	(standard)	1 (4%)	1 (4%)
	(intervention)	0 (0%)	0 (0%)
Work around home	(standard)	1 (4%)	0 (0%)
	(intervention)	0 (0%)	0 (0%)
Not being able to do the things that you used to do	(standard)	5 (20%)	1 (4%)
	(intervention)	2 (15.4%)	0 (0%)
Anxiety	(standard)	3 (12%)	0 (0%)
	(intervention)	0 (0%)	0 (0%)
Feeling down or depressed	(standard)	3 (12%)	1 (4%)
	(intervention)	2 (15.4%)	0 (0%)
Feelings of sadness	(standard)	3 (12%)	0 (0%)
	(intervention)	1 (7.7%)	0 (0%)
Fear about the cancer spreading	(standard)	6 (24%)	4 (16%)
	(intervention)	1 (7.7%)	0 (0%)
Worry that the results of treatment are beyond your control	(standard)	6 (24%)	2 (8%)
	(intervention)	1 (7.7%)	0 (0%)
Uncertainty about the future	(standard)	9 (36%)	0 (0%)
	(intervention)	1 (7.7%)	0 (0%)
Learning to feel in control of your situation	(standard)	7 (28%)	0 (0%)
	(intervention)	1 (7.7%)	0 (0%)
Keeping a positive outlook situation	(standard)	3 (12%)	0 (0%)
	(intervention)	0 (0%)	0 (0%)
Fear about death and dying	(standard)	4 (16%)	1 (4%)
	(intervention)	0 (0%)	0 (0%)
Changes in sexual feelings	(standard)	5 (20%)	2 (8%)
	(intervention)	1 (7.7%)	0 (0%)
Changes in sexual relationships	(standard)	5 (20%)	2 (8%)
	(intervention)	1 (7.7%)	0 (0%)
Concerns about the worries of those close to you	(standard)	5 (20%)	2 (8%)
	(intervention)	1 (7.7%)	0 (0%)
More choice about which cancer specialist to see	(standard)	6 (24%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)
More choice about which hospital you attend	(standard)	0 (0%)	0 (0%)
	(intervention)	0 (0%)	0 (0%)
Reassurance by medical staff that the way you feel is normal	(standard)	2 (8%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)
Hospital staff attending promptly to your physical needs	(standard)	0 (0%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)
Hospital staff acknowledging, and showing sensitivities to your emotional needs	(standard)	0 (0%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)
Being given written information about the important aspects of your care needs	(standard)	4 (16%)	3 (12%)
	(intervention)	0 (0%)	0 (0%)
Being given information (written diagrams, drawings) about managing your illness and side-effects at home			
	(standard)	6 (24%)	1 (4%)
	(intervention)	0 (0%)	0 (0%)
Being given explanations for those test for which you would like explanations	(standard)	7 (28%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)
Being adequately informed about the benefits and side-effects of treatment before you choice to have them			
	(standard)	4 (16%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)
Being informed about test results as soon as feasible	(standard)	3 (12%)	5 (20%)
	(intervention)	1 (7.7%)	0 (0%)
Being informed about cancer that is under control or diminishing	(standard)	5 (20%)	2 (8%)
	(intervention)	0 (0%)	0 (0%)

Being informed about the things that you can do to get well	(standard) (intervention)	4 (16%) 0 (0%)	2 (8%) 0 (0%)
Having access to professional counselling	(standard) (intervention)	3 (12%) 0 (0%)	1 (4%) 0 (0%)
Being given information about sexual relationships	(standard) (intervention)	3 (12%) 0 (0%)	1 (4%) 0 (0%)
Being treated like a person not just another case	(standard) (intervention)	2 (8%) 0 (0%)	1 (4%) 0 (0%)
Being treated in a hospital or clinic that is physically pleasant as possible case	(standard) (intervention)	0 (0%) 0 (0%)	2 (8%) 0 (0%)
Having one member of hospital staff with whom you can talk to	(standard) (intervention)	5 (20%) 0 (0%)	0 (0%) 0 (0%)